



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2009-0034]

Pre-harvest Management to Reduce Shiga toxin-producing

Escherichia coli Shedding in Cattle

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and opportunity for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of its updated guidance document on pre-harvest management controls and intervention options for reducing Shiga toxin-producing Escherichia coli (STEC) shedding in cattle. In addition, this notice summarizes and responds to comments received on the guidance document and on the pre-harvest management issues that FSIS raised in a previous Federal Register notice and public meeting.

DATES: Written comments may be submitted until 30 days after issuance of this notice.

ADDRESSES: FSIS invites interested persons to submit comments on the guidance document for the pre-harvest management controls and intervention options for reducing STEC. Comments may be submitted by either of the following methods: Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page

or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs, etc.: Send to Docket Room Manager, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW, Room 8-163B, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS - 2009-0034. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW, Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

A downloadable version of the revised guidance document is available to view and print at (add link to CG). No hard copies of the guidance document have been published.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495, or by Fax: (202) 720-2025.

SUPPLEMENTARY INFORMATION:

Background

On May 14, 2010, FSIS announced the availability of a guidance document on pre-harvest management to reduce STEC shedding in cattle and requested comment on the guidance (75 FR 27288). The guidance provided beef slaughter establishments with an informational resource on pre-harvest management controls and interventions for reducing the shedding of STEC in feces during cattle production. The document provided an overview of the status of pre-harvest control and intervention strategies discussed in the scientific literature to reduce STEC shedding in cattle. The document covered the intervention strategies, state of findings, and links to additional scientific references for the strategies discussed.

The guidance explained that STEC shedding by cattle is a hazard that occurs at pre-harvest and in the holding pens at the establishment. STEC shedding may result in contamination of the hides and transfer of STEC to the carcass during carcass dressing. Establishments may address this hazard by incorporating into their HACCP plans or prerequisite programs purchase specifications, other programs, or agreements that

require that their suppliers implement certain pre-harvest management controls.

As the guidance also explained, FSIS recommends pre-harvest interventions as the first control steps in an integrated beef products safety system. FSIS recommends that slaughter establishments receive their cattle from beef producers that implement one or more documented pre-harvest management practices to reduce STEC shedding.

In September 2011, FSIS declared six STEC strains - O26, O45, O103, O111, O121, and O145 - in addition to O157:H7, as adulterants in beef (76 FR 58157). FSIS has updated the guidance document to address the additional adulterant STEC. In addition, in response to comments, FSIS removed statements from the document that may have recommended a particular pre-harvest intervention or practice over another.

On November 9, 2011, FSIS, the Animal and Plant Health Inspection Service (APHIS), and the Agricultural Research Service (ARS) hosted a public meeting seeking input on pre-harvest pathogen control strategies designed to reduce the likelihood that beef will be contaminated with pathogens of public health concern, such as Shiga toxin-producing E. coli and Salmonella, during the slaughter process. One of FSIS's goals for the public meeting was to obtain information that it could

use to improve the pre-harvest guidance (76 FR 63901) that it had issued.

At the public meeting, presentations were made on "The Control of Foodborne Pathogens in Cattle: Efficacy, Adoption, and Impact on Public Health" and "Public Health and Pre-Harvest Interventions - What is the potential." Additionally, round table discussions were held on "What factors influence the shedding of Salmonella and E. coli O157:H7 and other STEC (e.g., age of cattle, stress conditions)," "What effective and practical mitigations are available to reduce the pathogen load in general, and Salmonella and STECs specifically, in cattle before slaughter," and "How can producers, processors, and government work together to promote adoption of pre-harvest food safety mitigations." Individuals from all three Federal Agencies, industry, and industry associations were present. (See links to the meeting records later in this document.)

Meeting participants sought clarification of what super shedders are, and how they would be identified during production. They felt strongly that the United States should build upon successful mitigations used in foreign countries; allow the market to drive the value of any particular mitigation technology, including vaccines; and streamline the regulatory approval process. They recommended also that there be sustained discussions among Federal, industry, and academic partners to

identify and put into practice pre-harvest mitigations for reducing foodborne hazards and beef.

FSIS has reviewed the comments from the public meeting, and based on its review, it has developed the updated guidance document whose availability FSIS is announcing. The updated document sets out innovative ways to control pathogens in beef at pre-harvest and pre-harvest pathogen control strategies for animals presented for slaughter.

Comments and Responses

FSIS received four comments in response to the May 2010 announcement of the availability of the guidance document. In addition, the Agency received three comments in response to the October 2011 notice "Pre-harvest Food Safety for Cattle Public Meeting" (76 FR 63901), and five comments at the November 2011 public meeting. The comments were from consumer groups and an industry trade associations. Following is a summary of the comments in response to the guidance and the public meeting and FSIS's responses.

General Comments

Comment: Industry trade associations expressed concern that the guidance document established requirements. One commenter was especially concerned that FSIS' inspection program personnel would use the guidance to take regulatory action.

Response: This guidance document, like all FSIS guidance documents, represents the Agency's current thinking on pre-harvest intervention strategies and does not establish requirements. There are no regulatory requirements for establishments embodied in the intervention and management practices outlined in this document. The Agency removed from the pre-harvest guidance document any statements that could indicate a preference for one pre-harvest intervention over another. An establishment is not required to use the interventions or management practices outlined in the guidance document and may take an alternative approach to reduce STEC shedding in cattle for slaughter.

Comment: Several comments stated that USDA should be more involved in pre-harvest food safety research. An advocacy group suggested that bacterial isolates collected from a statistically valid and nationally representative sample of cattle entering slaughter could provide information about the bacterial load on the animals. A University professor asked that the Agency consider a research exemption to study STEC in industry environments to overcome the reluctance of packers to permit scientists to carry out studies in their facilities.

Response: FSIS recognizes the importance of determining the incoming bacterial load on cattle presented for slaughter, and of giving researchers access to the industry environment.

However, FSIS does not advocate the introduction of pathogens into official establishments. Raw non-intact beef or intact beef intended to be used to produce raw non-intact beef is adulterated if contaminated with the STEC that FSIS has identified as adulterants. Therefore, establishments would have to take steps to effectively address any STEC detected during research that could contaminate raw non-intact product.

FSIS food safety research priorities include pre-harvest research initiatives, such as research on the effect of pre-harvest interventions on finished products; on the effectiveness of integration of one or more pre-harvest or post-harvest interventions as a control strategy; and identification or development of pre- and post-harvest interventions to reduce pathogen and chemical hazards in veal.

See FSIS website:

[http://www.fsis.usda.gov/wps/portal/fsis/topics/science/food-safety-research-priorities.](http://www.fsis.usda.gov/wps/portal/fsis/topics/science/food-safety-research-priorities)

Vaccines, New Technologies, and Best Practices

Comment: Several commenters recognized that FSIS does not have authority to approve or regulate vaccines but encouraged the Agency to collaborate with APHIS' Center for Veterinary Biologics to provide a comprehensive view of the steps required for vaccine approval, one that covers foodborne illness pathogens as well as animal disease pathogens. Commenters

underscored the need for industry to use new technologies and best practices, such as developed vaccines or the sanitary care of animals. An animal health care company noted that any of the interventions used on the farm would show increasing benefit the longer they are used on the live animal. A trade group representing meat packing and processing establishments recommended that the above-mentioned agencies collaborate with beef stakeholders through the E. coli Coalition and other industry efforts focused on beef safety.

Response: Hosting the public meeting is a clear example of successful collaboration among the three agencies.

Additionally, the guidance document provides innovative ways to control pathogens in beef pre-harvest and when presented for slaughter. FSIS disagrees that any intervention used on the farm would show increasing benefit the longer it is used on the live animal. The effectiveness of select interventions may increase, e.g., husbandry practices, but not all the interventions described in the guidance document will provide an increasing benefit over time.

Additionally, FSIS's Office of Policy and Program Development provided updates to the National Advisory Committee on Meat and Poultry Inspection (NACMPI) on Salmonella and pre-harvest initiatives based on a NACMPI committee 2013 recommendation, which included that FSIS will continue to have

discussions on pre-harvest issues among the federal government, industry, and academia and to re-issue the pre-harvest guidance document and respond to comments on the previous Federal Register Notice (78 FR 77643 and <http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/past-meetings>).

Regarding working with external partners, FSIS is bringing together the groups that actually review the submissions that come to them on pre-harvest interventions along with ARS, which develops a lot of the research, to see whether FSIS and ARS could facilitate an expedited process. FSIS has met with the Food and Drug Administration on the pre-harvest intervention submissions that have been received by that agency and on the criteria that it uses to review them. Additionally, FSIS is in contact with APHIS regarding vaccines. Finally, FSIS is working with industry and academic partners to identify and incorporate pre-harvest mitigation strategies for reducing foodborne hazards in beef and poultry into guidance documents.

Antimicrobial Resistance

Comment: Two advocacy groups expressed concern about the use of antibiotics in cattle that may lead to antibiotic resistance and requested that FSIS take a more active role in promoting pre-harvest steps aimed at reducing the selection from and spread of antimicrobial resistance. One commenter suggested

that current production practices, involving dependence on the non-therapeutic use of antibiotics and overcrowding in feedlots, create conditions that are ideal for the development and spread of antibiotic-resistant pathogens.

Response: FSIS recognizes the complexity of the antimicrobial resistance issue. Given this complexity, and the limits on FSIS's ability to address this issue, in the guidance document, FSIS discusses studies that focus on the effects of various strategies to reduce STEC shedding in cattle. These strategies include the use of medications, such as antibiotics, as well as non-medicinal approaches. The guidance document discusses the use of antibiotics, such as ionophores, neomycin sulfate, tetracycline, and oxytetracycline, in cattle and their effect on STEC shedding.

FSIS participates in the National Resistance Monitoring System (NARMS) sampling program, which is a surveillance sampling program that provides FSIS, FDA, and other interested agencies with data on the presence of selected enteric microorganisms in food animal species. The sampling for antibiotic residues is conducted as part of NARMS.

Comment: A consumer advocacy group stated that, while the pre-harvest meeting discussions focused mainly on the control of E. coli, FSIS should recognize that there are significant pre-harvest issues related to the control of Salmonella. The

commenter noted that it has petitioned FSIS to declare four strains of Salmonella to be adulterants when antibiotic resistant and when found in FSIS-regulated products, considering it to be within FSIS' authority to declare these antimicrobial resistant strains to be adulterants.

Response: FSIS is reviewing the group's petition and expects to respond to the petition in the coming months and will post the response on the FSIS web site.

More broadly, FSIS's focus for the guidance document is to provide beef slaughter establishments with an informational resource on pre-harvest management controls and interventions for reducing STEC shedding in beef cattle production. In regards to Salmonella, FSIS announced an action plan posted at: <http://www.fsis.usda.gov/wps/wcm/connect/aae911af-f918-4fe1-bc42-7b957b2e942a/SAP-120413.pdf?MOD=AJPERES>.

Pre-harvest contamination can affect the level of Salmonella on FSIS-regulated products. Synthesizing information on pre-harvest interventions from previous and on-going FSIS activities, and other information available from industry, could help decrease the prevalence or levels of Salmonella on FSIS-regulated products. As stated in the action plan, FSIS will continue to work with industry members to identify best practices for pre-harvest. FSIS will also organize and host a meeting to focus on pre-harvest issues for poultry. FSIS will

then use the information gathered at that meeting to inform future policies and best-practice guidelines.

Communication with Stakeholders

Comment: An animal health care company encouraged the public meeting organizers to follow-up with participants by communicating potential results or implications of the meeting.

Response: The Agency agrees that stakeholders should be kept informed. The transcript of the meeting is available on the Agency's website at <http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/past-meetings/past-meetings-2011>. Notes from the round table discussions held at the meeting are available at http://www.fsis.usda.gov/wps/wcm/connect/2091b3b8-2d81-4531-81b7-f05369a9a16f/Pre-Harvest_FS_Notes.pdf?MOD=AJPERES.

An outgrowth of the meeting is the Agency's updated guidance document. FSIS fully considered the comments made during and in response to the meeting in updating the guidance.

Comment: Three commenters stated that the May 2010 guidance document lacked scientific rigor, was inconsistent in the recommendations, and generally included practices that did not work. For example, a trade association disagreed that antibiotics would be effective in preventing shedding of E. coli O157:H7 in cattle. One commenter felt there would be confusion in the use of both scientific and trade names for antibiotics.

Response: It is important that establishments, particularly small and very small establishments, have access to a full range of scientific and technical information to assist them in establishing safe and effective HACCP systems, including information on pre-harvest management strategies that an establishment may choose to incorporate to reduce the incoming bacterial load into their process. For example, the guidance draws on a number of studies on feed types, feed additives, fasting, and their effects on E. coli O157:H7 shedding, with some studies showing a decrease in E. coli O157:H7 shedding, while others showed an increase or no difference in E. coli O157:H7 shedding. In some studies, ractopamine was shown to decrease E. coli O157:H7 shedding, while in other studies it was shown to increase E. coli O157:H7 shedding. The Agency's intent in re-issuing the guidance document is to provide industry with a review of the literature on, and the current status of, pre-harvest interventions, management practices, and ongoing research. FSIS has removed statements from the document that may have recommended any particular pre-harvest intervention or practice over another one.

As stated above, there is no regulatory requirement for establishments to use the interventions or management practices outlined in the guidance document.

FSIS regards the use of both scientific and trade names for antibiotics as justified because the use of both is common in the scientific literature on pre-harvest interventions and management practices.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at <http://www.fsis.usda.gov/federal-register>.

FSIS will also make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/subscribe>.

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Dated: August 8, 2014.

Alfred V. Almanza,
Administrator.

[FR Doc. 2014-19172 Filed 08/12/2014 at 8:45 am; Publication
Date: 08/13/2014]